Applicants submit that claim 1 is not anticipated by Nakamura because Nakamura fails to teach each and every element of the claim. For example, claim 1 recites a moisture-sensitive product having a continuous length. A moisture-sensitive product is defined in the Specification as a product that, when exposed to moisture, including ambient humidity levels, rapidly stiffens and forms a cured splint or cast. *See* Specification, page 1, lines 19-21.

In contrast, nothing is identified in Nakamura that teaches a moisture-sensitive product as defined by the present invention. Instead, Nakamura teaches "wet tissues, i.e., fibrous materials, such as non-woven fabrics, woven fabrics, or gauze, impregnated with toilet water or cleaning solution...." Nakamura, column 1, lines 18-20. The wet tissues taught by Nakamura, however, do not anticipate the moisture-sensitive product of the present invention, e.g., they do not rapidly stiffen and form a cured splint or cast.

The Office Action, however, alleges that "product 3 taught by Nakamura may be defined as 'moisture sensitive' in the broadest sense of the word; the moisture content of the product 3 directly affects its function and usability." This definition of "moisture-sensitive" is not consistent with the definition given by Applicants in the Specification as stated above. Words must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 13 U.S.P.Q. 1320, 1322 (Fed. Cir. 1989). Here, Applicants have provided a clear definition in the Specification for "moisture-sensitive." As Nakamura does not teach a "moisture-sensitive" product consistent with this definition, Nakamura fails to anticipate claim 1.

Further, claim 1 recites a product having a continuous length, the product being folded into a packaged configuration including a plurality of sections arranged within the interior and along the pouch length. Each section of the folded product includes at least two folds and a segment spanning therebetween, the segment also extending along the pouch length. "Extending along the pouch length" is clearly illustrated (see e.g., Figures 2 and 4) and also described in the specification (*see* e.g., page 10, lines 30-32) as segments that are generally "*parallel* to the pouch length or otherwise correspond with the dispensing direction." For example, as illustrated in Figure 3A, one embodiment of the present invention includes a product 300 that is folded to form a series of repeating S-shaped sections 302 along the length of the pouch 200. In the

illustrated embodiment, a segment 302b spans between two folds 306a and 306b, and extends *along the pouch length.*

The alleged "segment" of Figure 13 of Nakamura does not extend along the pouch length, i.e., there is no identified segment that is parallel to the pouch length, as claimed. Nonetheless, the Office Action alleges that a "component" of the Nakamura segment will extend upwardly along the pouch length "due to the helical arrangement." *See* Office Action, page 7. Applicants submit that any alleged component that may extend upwardly in the embodiment of Figure 13 of Nakamura does not anticipate a segment extending along (parallel to) the pouch length as recited in claim 1. In fact, the actual "segments" of Nakamura are almost completely transverse to the pouch length rather than parallel thereto. As a result, Nakamura fails to anticipate claim 1.

Even if the clear language of the specification were lacking in this instance, Applicants submit that claim 1 would still be novel in view of Nakamura. That is, to equate the claim language (e.g., *segment extending* along the pouch length) to a mere geometric aspect of the helically wound product of Nakamura would result in a conclusion that *all* three-dimensional objects necessarily *extend* in every conceivable direction. Such a conclusion is inaccurate.

For at least the above reasons, Applicants submit that claim 1 is not anticipated by Nakamura. Reconsideration and withdrawal of this rejection are therefore requested.

II. Whether Claim 1 is anticipated by Cernohous (WO 96/20884) under 35 U.S.C. § 102(b)

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Cernohous. Applicants traverse this rejection.

Applicants submit that Cernohous fails to teach each and every element recited in claim 1. For example, Cernohous does not teach a moisture-sensitive product (e.g., a product that rapidly stiffens and forms a cured splint or cast when exposed to moisture, *See* Specification, page 1, lines 19-21), as recited in claim 1. Instead, Cernohous teaches a sorbent nonwoven web that contains microfibers so that mass quantities of liquid can be absorbed. See Specification at page 5, lines 5-6. This reason alone is sufficient to remove Cernohous as an anticipatory reference. Nonetheless, the following remarks are additionally provided.

If the "sections" (e.g., a section, by claim definition, includes two folds and a segment spanning therebetween) of Cernohous are interpreted to be arranged "along the pouch length" (i.e., vertically in Figure 1), then the "segments" of Cernohous et al. necessarily extend *transverse* to the length rather than along the pouch length as claimed. That is, the segments and the sections do not both extend along the pouch length as claimed and illustrated (*see*, e.g., Figures 2 and 4). Thus, Cernohous does not anticipate claim 1.

The Office Action asserts, however, that Cernohous teaches that the thickness of the material extends along the pouch thickness. Applicants traverse this assertion. First, claim 1 recites that the segment extends along the pouch length, not along the pouch thickness as asserted by the Office Action. Moreover, as mentioned above, the element "the segment also extending along the pouch length" recited in claim 1 is defined in the Specification as a segment that is generally parallel to the pouch length or otherwise corresponds to the dispensing direction. *See* Specification, page 10, lines 30-32. The Office Action has not identified a corresponding feature of the product in Cernohous.

Further, claim 1 recites that the segment extends along the pouch length while also spanning between the at least two folds of each section. As a result, the "thickness" of the material taught by Cernohous cannot be equivalent to the segment recited by claim 1 because the *"thickness"* of the Cernohous product does not span between two folds.

For at least the above reasons, Applicants submit that claim 1 is not anticipated by Cernohous. Reconsideration and withdrawal of this rejection are therefore requested.

III. Whether Claims 2, 5-9, 13-15, 17-20, and 22 are anticipated by Nakamura under 35 U.S.C. § 102(b)

Claims 2, 5-9, 13-15, 17-20, and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Nakamura. Applicants traverse this rejection.

Claims 2, 5-9, 13-15, 17-20, and 22, each of which depend, either directly or ultimately, from claim 1, are not anticipated by Nakamura for the same reasons as given above for the anticipation rejection of claim 1 in view of Nakamura. In addition, claims 2, 5-9, 13-15, 17-20, and 22 each recite additional, patentable elements that further support patentability when combined with claim 1.

For example, claim 8 recites a compression device proximate the opening of the pouch. The compression device substantially conforms the pouch to the product both during and after dispensing. *See* e.g., Specification, page 3, lines 24-26; page 16, lines 1-2 and 12-13.

Nakamura, on the other hand, does not teach a compression device proximate the opening 12 of container body 10. *See* Nakamura, Figure 13. The Office Action alleges that flap 14 may function as a compression device. However, there is no teaching identified that the flap 14 is a compression device as claimed, e.g., there is no teaching identified that the flap 14 can conform the pouch to the product. Rather, the flap is for repeatedly opening and sealing the dispensing opening 12 of the container body 10. *See* Nakamura, column 14, lines 38-39.

For these and other reasons, Applicants submit that claims 2, 5-9, 13-15, 17-20, and 22 are not anticipated by Nakamura. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

IV. Whether Claims 1, 2, 4-10, 12-16, 25-28, 32, 38-46, and 61-62 are anticipated by Parker et al. (U.S. Patent No. 5,003,970) under 35 U.S.C. § 102(b)

Claims 1, 2, 4-10, 12-16, 25-28, 32, 38-46, and 61-62 were rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Applicants traverse this rejection for at least the following reasons.

Claims 1 and 61

With respect to claims 1 and 61, Applicants submit that Parker et al. fails to teach each and every element of the claims and, for that reason, is not an anticipatory document.

Claim 1 recites a continuous length product folded into a packaged configuration including a plurality of sections arranged along the pouch length, where each section includes at least two folds and a segment spanning therebetween, the segment also extending along the pouch length. Claim 61 further recites a moisture-curable orthopedic splinting/casting product.

Parker et al., on the other hand, is directed to a roll form medical bandaging product. In particular, Parker et al. describes a container 31 with an elongate dispensing sleeve 32 that has an openable end 33 through which the medical material 14 in the container 31 is dispensed. A coil of the medical material 14 is positioned in an enlarged product storage package 34 that is integral

and communicates with dispensing sleeve 32 (*see*, e.g., column 6, lines 22-28; Figures 11 and 14).

Applicants submit that the Office Action fails to identify a continuous length product folded into a packaged configuration including a plurality of sections arranged along the pouch length, where each section includes at least two folds and a segment spanning therebetween, the segment also extending along the pouch length (as discussed above, the phrase "extending along the pouch length" is defined in the specification and illustrated in the Figures as being oriented parallel to the pouch length or otherwise corresponding to the dispensing direction, *see* e.g., Specification at page 10, lines 30-32).

The Office Action appears to rely on Figure 13 of Parker et al. to substantiate this rejection. In this view, a cross section, taken along line 13-13 of Figure 12, shows the medical material which includes a "substrate 16 comprised of a suitable number . . . of overlaid fibers of a . . . fabric . . . contained within a tubular wrapping 18 [see Figure 5] which is formed of a soft, flexible . . . fiber . . . to provide a cushioning protective layer between the skin of the patient and substrate 16." *See* Specification, column 5, lines 24-32. That is, the medical material includes the substrate 16 and the wrapping 18.

The Office Action, apparently in view of Figure 13 of Parker et al., alleges that the patent teaches "a plurality of sections (the layers seen in Fig 13), . . . [with] each section comprising two folds (at the edges) and a spanning segment (the middle portion of a layer) which extends along the pouch length." *See* Office Action, page 3. Applicants submit, however, that such a configuration, even if disclosed by Parker et al., does not anticipate the claims.

For example, if the Office Action is relying on the two folds which are "at the edges" in Figure 13, then any alleged segment that "spans between" these two folds must necessarily extend between the edges, i.e., across the width of (transverse to) the material. Such a configuration is clearly not "along the pouch length" as claimed and described by Applicants. As a result, Parker et al. fails to anticipate claims 1 and 61 and the claims that depend therefrom.

It is further noted that the Office Action's rejection of claims 1 and 61 based on Figure 13 of Parker et al. relies not on the configuration of the medical material itself, but rather on the configuration of the substrate fibers that form only a portion of the medical material. That is, the Office Action is equating the weave configuration of the fiber substrate of the medical material

14 to the folded configuration of the actual moisture-sensitive product claimed by Applicants. The actual medical material or product of Parker et al. is the actual rolled product illustrated in Figure 14. Comparison of the fibers of Parker to the product of the present invention is insufficient to establish anticipation.

Because anticipation requires that the identical invention be found in as complete detail as is recited in the claim (*see* MPEP 2131), the Office Action has not met the burden for establishing anticipation based on Parker et al. For at least these reasons, it is submit that claims 1 and 61 are not anticipated by Parker et al. Reconsideration and withdrawal of this rejection are requested.

Claims 2, 4-10, and 12-16

With regard to claims 2, 4-10, and 12-16, all of which depend, either directly or ultimately, from independent claim 1, claims 2, 4-10, and 12-16 are not anticipated by Parker et al. for the same reasons as presented above for claim 1. In addition, claims 2, 4-10, and 12-16 each recite additional elements that further support patentability when combined with claim 1.

For example, claim 8 recites that the apparatus of the present invention further includes a compression device proximate the opening. The compression device is defined as a device that substantially conforms the pouch to the product both during and after dispensing. *See* e.g., Specification, page 3, lines 24-26. The compression device is provided to reduce moisture intrusion during dispensing of the product. *See* Specification, page 7, lines 30-33. In contrast, Parker et al. does not teach a compression device that reduces moisture intrusion during dispensing of the product.

Nonetheless, the Office Action alleges that clamp 36 of Parker et al. is a compression device within the meaning of claim 8. However, Applicants submit that the clamp 36 cannot reduce moisture intrusion during dispensing of the product because the clamp 36 must be removed in order for the user to grasp the product to be dispensed. *See* Parker et al., column 6, lines 56-58 ("A desired length of medical material 14 is dispensed by removing clamp 36 or unzipping zippers 38 and grasping the exposed end of the medical material 14."). Therefore, Parker et al. does not teach a compression device as claimed and, as such, claim 8, as well as claims 9-10 and 12 (which depend from claim 8) are not anticipated by Parker et al.

With regard to claims 15 and 16, Parker et al. does not teach a folded product configuration that includes at least two sections that each form an S-shape. That is the material 14 (the substrate 16 and a single tubular sleeve 18) of Parker et al. does not include even a single section that forms an S-shape. *See,* e.g., Figures 4 and 5.

For at least the above reasons, Applicants submit that claims 2, 4-10, and 12-16 are not anticipated by Parker et al. Reconsideration and withdrawal are requested.

Claim 25

Claim 25 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Applicants traverse this rejection.

As discussed above, Parker et al. does not teach a compression device as claimed and defined by the present invention, e.g., a device that substantially conforms the pouch to the product. For example, the alleged compression device or Parker et al., i.e. clamp 36, has to be removed prior to dispensing material 14 and therefore cannot reduce moisture intrusion during dispensing of material 14.

Moreover, contrary to the Office Action, there is no teaching that Figure 11 (or any other portion of Parker et al.) shows the clamp 36 conforming the shape of the pouch to the product (*see* Office Action, page 7). In fact, the specification (*see* e.g., column 6, lines 61-64) and the figures (see e.g., Figure 12) of Parker et al. indicate that the clamp 36 or zipper 38 function by tucking the material back into the sleeve and sealing the sleeve with the clamp or zipper.

As a result, Parker et al. does not anticipate claim 25. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 26-28, 32, and 38-41

Claims 26-28, 32, and 38-41, each of which depend, either directly or ultimately, from independent claim 25, are not anticipated by Parker et al. for the same reasons as presented above for claim 25. In addition, claims 26-28, 32, and 38-41 each recite additional elements that further support patentability when combined with claim 25. As a result, it is requested that each dependent claim be examined based upon its own elements.

For example, the Office Action does not identify any teachings that anticipate the parallel closure device of claim 28. Moreover, claim 32 recites that the compression members conform the shape of the first end of the pouch to the shape of the product as the product is dispensed from the pouch through the opening. As mentioned above, the alleged compression device taught by Parker et al., i.e. clamp 36, must be removed prior to dispensing material 14; therefore, the clamp 36 cannot conform the shape of the first end of the pouch to the shape of the product as the product is dispensed from the pouch through the opening.

For these and other reasons, Applicants submit that claims 25-28, 32, and 38-40 are not anticipated by Parker et al. Reconsideration and withdrawal of this rejection are therefore requested.

Claim 42

Claim 42 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Applicants traverse this rejection.

Applicants submit that Parker et al. does not teach each and every element of claim 42. For example, Parker et al. does not teach both a compression device and a sealing device. In fact, as mentioned above, Parker et al. does not teach a compression device at all.

The Office Action alleges, however, that the two curved arms of clamp 36 (of Parker et al.) are equivalent to the compression device having two opposing compression members as claimed. Applicants strenuously disagree. The two curved arms of clamp 36 (or any other part of the clamp for that matter) are not identified as being capable of doing anything but apparently biasing the clamp , i.e., sealing device, to seal the sleeve after the product has been dispensed.

As Parker et al. fails to teach the identical invention in as complete detail as recited within claim 42, it fails to anticipate the claim. Reconsideration and allowance are therefore requested.

Claims 43-46

Claims 43-46 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Applicants traverse this rejection as these claims depend, either directly or ultimately, from independent claim 42. Thus, claims 43-46 are not anticipated by Parker et al. for the same

reasons as presented above for claim 42. In addition, claims 43-46 each recite additional elements that further support patentability when combined with claim 42.

For example, claim 43 provides a frame assembly (*see* e.g., Figures 8 and 9) operatively coupling the compression device to the sealing device. Once again, because Parker et al. fails to even disclose a compression device as claimed, it necessarily cannot disclose a frame assembly associated therewith. Parker et al. therefore cannot anticipate claim 43.

The Office Action, however, alleges that the semi-circular portion of clamp 36 taught by Parker et al. is a "frame assembly" which couples the compression and sealing devices together. However, the Office Action has not identified any portion of the clamp 36 which functions as a compression device. Therefore, even considering all of the assumptions made by the Office Action, the clamp 36 of Parker et al. fails to teach a frame assembly that operatively couples a "compression device" to the sealing device, as is recited in claim 43.

For at least the above reasons, Applicants submit that claims 43-46 are not anticipated by Parker et al. Reconsideration and withdrawal of this rejection are therefore requested.

Claim 62

Claim 62 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Applicants traverse this rejection.

Applicants submit that Parker et al. does not teach all of the elements of claim 62. For example, claim 62 recites a compression device that includes a first compressible member and a second, opposing compressible member. The first and second compressible members are adapted to substantially conform the shape of the first end of the pouch to the shape of the product. In contrast to claim 62, nothing is identified in Parker et al. that the clamp 36 has a first and second compressible member. While the Office Action alleges that the flat portions of clamp 36 are the equivalent of the first and second compressible members, this allegation conflicts with the earlier allegation (made with reference to claims 42-46) that the flat portions are equivalent to sealing members of a sealing device.

Further, as mentioned above, the clamp 36 taught by Parker et al. must be removed prior to dispensing material 14. In fact, Parker et al. makes clear that the material must be "tucked back in the pouch" before the clamp 36 can even be used (*see* column 6, lines 61-64). Such a

clamp clearly fails to anticipate a compression device of that "substantially conforms the shape of the first end of the pouch to the shape of the product."

For at least these reasons, Applicants submit that claim 62 is not anticipated by Parker et al. Reconsideration and withdrawal of this rejection are requested.

V. Whether claim 23 is unpatentable over Nakamura under 35 U.S.C. § 103(a)

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakamura. Applicants traverse this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Claim 23, which depends from independent claim 1, includes all of the elements recited in claim 1. As mentioned above in regard to the 35 U.S.C. § 102(b) rejection of claim 1, Nakamura does not teach all of the elements of claim 1. For example, Nakamura does not teach a moisture-sensitive product within the clear meaning given in the present invention. Further, Nakamura does not teach the plurality of sections and the configuration of the segments (e.g., along the pouch length) as recited in claim 1 (see discussion above regarding anticipation rejection of claim 1 in view of Nakamura). Claim 23 recites additional elements that further support patentability when combined with claim 1.

As noted above, a proper *prima facie* obviousness rejection requires identification of some motivation or suggestion to modify the cited reference to reach the claimed invention. No such motivation or suggestion is identified with respect to the features that are not disclosed in Nakamura.

For at least the above reasons, Applicants submit that claim 23 is patentable over Nakamura. Reconsideration and withdrawal of this rejection are therefore requested.

VI. Whether claim 29 is unpatentable over Parker et al. in view of Ausnit (U.S. Patent No. 4,703,518) under 35 U.S.C. § 103(a)

Claim 29 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Parker et al. in view of Ausnit. Applicants traverse this rejection.

Claim 29, which depends from claim 25, is not *prima facie* obvious because the cited references do not teach or suggest all of the elements of claim 29. As mentioned above in regard to the 35 U.S.C. § 102(b) rejection of claim 25, Parker et al. does not teach all of the elements of claim 25. For example, Parker et al. does not teach or suggest a compression device that substantially conforms the pouch to the product. The addition of Ausnit does nothing to address the above-mentioned deficiencies of Parker et al.

Further, no motivation or suggestion is identified in the Office Action to combine the plastic zipper taught by Ausnit with the container taught by Parker et al. For example, the zipper taught by Ausnit requires that the bag to which the zipper is attached have side seal seams 69 and holes 68 formed in the side seal seams. *See* Ausnit, column 4, lines 23-25. There is no teaching or suggestion identified that holes may be made in dispensing sleeve 32 of Parker et al. to accommodate the zipper mechanism/holes taught by Ausnit. In fact, Parker et al. teaches away from including such holes as they may allow air to enter the sleeve.

For the above reasons, Applicants submit that claim 29 is not *prima facie* obvious in view of Parker et al. and Ausnit. Reconsideration and withdrawal of this rejection are requested.

VII. Whether claims 11, 21, and 30-31 are unpatentable over Parker et al. under 35 U.S.C. § 103(a)

Claims 11, 21, and 30-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Parker et al. Applicants traverse this rejection.

Claims 11 and 21

Parker et al. fails to render claims 11 and 21 obvious for several reasons. For example, Parker et al. fails to teach or suggest all of the elements of claim 1 from which these claims depend. As mentioned above in regard to the 35 U.S.C. § 102(b) rejection of claim 1, Parker et al. fails to teach, or even suggest, a moisture-sensitive product that is folded into a packaged

configuration, wherein the packaged configuration includes a plurality of sections arranged within the interior and along the pouch length and further wherein each section of the packaged configuration includes at least two folds and a segment spanning therebetween, the segment of the packaged configuration also extending along the pouch length.

Instead, Parker et al. teaches a medical material 14 that is in a coiled packaged configuration. *See* Parker et al., column 4, lines 46-48; Figure 14. The coiled *packaged configuration* of Parker et al. does not have any folds, as is clearly seen in Figure 14. Further, there is no suggestion in Parker et al. to fold the product as claimed by Applicants.

In addition, claims 11 and 21 each recite additional elements that further support patentability when combined with claim 1. For example, claim 11 recites that each compression member includes a foam pad. The Office Action alleges that it would have been obvious to incorporate foam padding into the compression members of clamp 36 disclosed in Parker et al. in order to prevent damaging pouch 32. However, as mentioned above, Parker et al. does not teach or even suggest a compression device that includes two opposing and compressible members biased towards one another, as is recited by claim 10 (from which claim 11 depends). Rather, Parker et al. teaches only a sealing device to seal the package shut. There is no teaching, suggestion, or motivation identified in Parker et al. that the compressible members would be beneficial to sealing.

The Office Action does not appear to address claim 21. Claim 21 provides that at least two sections each form a mushroom-shape. As a result, Applicants assume that claim 21 is allowable and notice to that effect is requested.

Claims 30 and 31

Applicants further submit that claims 30 and 31, which depend from independent claim 25, are not *prima facie* obvious because Parker et al. does not teach or suggest all of the elements of claims 30 and 31. For example, as mentioned above, Parker et al. fails to teach or suggest a compression device that substantially conforms the pouch to the product. Further, Parker et al. fails to teach or suggest a suspension member coupled to the pouch, as is specifically recited in claims 30 and 31.

For the above reasons, Applicants submit that claims 11, 21, 30 and 31 are not *prima facie* obvious in view of Parker et al. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Summary

It is submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. § 1.10:

The undersigned hereby certifies that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 Box AF
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